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Patent Application

What is claimed:

1. A spray dried powder composition comprising IL-4R.

5 2. The powder composition of claim 1, having a monomer content and an aggregate level that is essentially unchanged relative to that of its pre-spray dried solution or suspension.

10 3. A storage stable powder composition of either claim 1, characterized by a decrease in monomer content as compared to that of its pre-spray dried solution or suspension of not more than 5% when determined after storage of said composition for 14 days at 25°C.

15 4. A storage stable powder composition of claim 3, characterized by an extent of formation of aggregates as compared to that of its pre-spray dried solution or suspension of not more than 5% when determined after storage of said composition for 14 days at 25°C.

20 5. The composition of claim 1, being moisture stable, exhibiting a minimal increase in aggregate formation and a minimal change in monomer content, as compared to the level of aggregate and monomer content of its pre-spray dried solution or suspension, under humid conditions.

25 6. The moisture stable composition of claim 5, characterized by a decrease in monomer content of not more than 10% when determined after storage of said composition for 14 days at 33% relative humidity.

30 7. The moisture stable composition of claim 5, characterized by a decrease in monomer content of not more than 7% when determined after storage of said composition for 14 days at 33% relative humidity.

8. The moisture stable composition of claim 5, characterized by a decrease in monomer content of not more than 5% when determined after storage of said composition for at least 14 days at 33% relative humidity.

5 9. The moisture stable composition of claim 5, characterized by a decrease in monomer content of not more than 5% when determined after storage of said composition for at least 14 days at 75% relative humidity.

10 10. The moisture stable composition of claim 5, characterized by formation of less than 10% insoluble aggregates after storage for 14 days at 33% relative humidity.

11. The composition of claim 1, characterized by formation of less than 7% insoluble aggregates upon storage for 14 days at 33% relative humidity.

15 12. The composition of claim 1, characterized by formation of less than 5% insoluble aggregates upon storage for 14 days at 33% relative humidity.

13. The composition of claim 1, characterized by formation of less than 5% insoluble aggregates upon storage for 14 days at 75% relative humidity.

20 14. The composition of claims 1, being temperature stable, exhibiting a minimal increase in aggregate formation and a minimal change in monomer content, as compared to the level of aggregate and monomer content of its pre-spray dried solutions or suspension, under extreme temperatures.

25 15. The temperature stable composition of claim 14, characterized by a decrease in monomer content of not more than 10% after storage for 14 days at 2 to 8°C or 40 to 50°C.

16. The temperature stable composition of claim 14, characterized by a decrease in monomer content of not more than 7% after storage for 14 days at 2 to 8°C or 40 to 50°C.

5 17. The temperature stable composition of claim 14, characterized by a decrease in monomer content of not more than 5% after storage for 14 days at 2 to 8°C or 40 to 50°C.

10 18. The temperature stable composition of claim 14, characterized by formation of less than 10% insoluble aggregates after storage for 14 days at 2 to 8°C or 40 to 50°C.

15 19. The temperature stable composition of claim 14, characterized by formation of less than 7% insoluble aggregates after storage for 14 days at 2 to 8°C or 40 to 50°C.

20 20. The temperature stable composition of claim 14, characterized by formation of less than 5% insoluble aggregates after storage for 14 days at 2 to 8°C or 40 to 50°C.

21. The powder composition of claim 1 in aerosolized form.

22. The powder composition of claim 1 substantially free from excipients.

25 23. The powder composition of claim 1, further comprising at least one pharmaceutically acceptable excipient.

30 24. The powder composition of claim 23, wherein the excipient is selected from the group consisting of carbohydrates, amino acids, oligopeptides, peptides, and proteins.

25. The powder composition of claim 24, wherein said carbohydrate is a sugar or sugar alcohol.

26. The powder compositions of claim 24, wherein said amino acid is a hydrophobic amino acid.

27. The powder composition of claim 23, wherein said excipient said excipient is selected from the group consisting of citrate salts, leucine, raffinose, zinc salts, and combinations thereof.

28. The powder composition of claim 23, wherein said excipient is a buffer.

29. The powder composition of claim 23, wherein said excipient is a divalent metal cation.

30. The powder composition of claim 1, characterized by an emitted dose of at least 30%.

31. The powder composition of claim 30, characterized by an emitted dose of at least 45%.

32. The powder composition of claim 31, characterized by an emitted dose of at least 60%.

33. The powder composition of claim 1, comprising particles having a mass median aerodynamic diameter (MMAD) of less than about 10 microns.

34. The powder composition of claim 1, comprising particles having a mass median aerodynamic diameter (MMAD) of less than about 5 microns.

35. The powder composition of claim 1, comprising particles having a mass median aerodynamic diameter (MMAD) of less than about 3.5 microns.

36. The powder composition of claim 1, comprising particles having a mass median diameter (MMAD) of between about 0.1 to 3 microns.

37. The powder composition of claim 1, wherein the residual moisture content is less than about 10% by weight.

38. The powder composition of claim 37, having a residual moisture content of less than about 5% by weight.

39. The powder composition of claim 1, wherein said composition has a bulk density ranging from about 0.1-10 g/cc.

40. The powder composition of claim 1, in a unit dosage form.

41. A method for aerosolizing an IL-4R dry powder composition, said method comprising:

- (a) providing an IL-4R composition of claim 1, and
- (b) dispersing said composition into a gas stream to form an aerosolized dry powder suitable for inhalation.

42. The method of claim 41, wherein said dispersing is achieved by means of a dry powder inhaler.

43. A method for preparing a dry IL-4R powder composition, said method comprising:

- (a) preparing a mixture or a solution of IL-4R in a solvent, and
- (b) spray-drying the mixture or solution to obtain the IL-4R powder of claim 1.